

PATENT

U.S. Pat. Appln. 09/377,795  
Attorney Docket No. UCSD-04523

#10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor Application of: Michael Karin *et al.*

Serial No.: 09/377,795

Group No.: 1635

Filed: 08/20/99

Examiner: Schmidt, M.

Entitled: **Gamma Subunit of Cytokine Responsive IKB-Alpha Kinase  
Complex And Methods Of Using Same**

**PETITION TO REVIVE  
UNINTENTIONALLY ABANDONED  
APPLICATION UNDER 37 C.F.R. § 1.137(b)** RECEIVED

BOX DAC

Assistant Commissioner for Patents  
Washington, D.C. 20231

JAN 14 2002

OFFICE OF PETITIONS

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)**

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: December 13, 2001

By: May Ellen Wark

Sir/Madam:

The above-identified Application became abandoned based on the failure of the Patent and Trademark Office to timely receive Applicants' response to the February 13, 2001, Office Action. The Examiner notified the Applicants of the absent response on September 10, 2001, and that the application stood abandoned as of August 13, 2001.

A thorough review and investigation of the above-mentioned file indicates that on June 11, 2001, the Applicants prepared and deposited with the U.S. Postal Service: 1) a communication responsive to the February 13, 2001, Office Action; 2) a sworn certificate of mailing under 37 C.F.R. § 1.18(a)(1)(i)(A); 3) a Request for a one month extension of time in which to respond to the outstanding Office Action; 4) a check in the amount of \$55.00 (the fee for the extension Request); an Appointment of Associate Attorneys; and 5) an Amendment Transmittal. Applicants note that each of the following papers, the Appointment of Associate Attorneys; the Amendment Transmittal; the Request For Extension Of Time; and the Applicants' Amendment And Response To The Office Action Mailed February 13, 2001,

respectively, deposited with the U.S. Postal Service on June 11, 2001, provided a sworn Certificate Of Mailing Under 37 C.F.R. § 1.8(a)(1)(i)(A).

The papers deposited by the Applicants with the U.S. Postal Service on June 11, 2001, have apparently never been received by the Patent and Trademark Office thus having been lost or mutilated by the U.S. Postal Service or the Patent and Trademark Office's receiving mailroom.

Applicants spent the time period from September 10, 2001, to the filing of the instant Petition discerning whether the retained copies of the above mentioned papers deposited with the U.S. Postal Service on June 11, 2001, provide a basis for disputing the abandonment of the instant Application, and preparing the instant Petition. Applicants have not, however, herein waived their right to present arguments that the instant application should not be abandoned. Accordingly, Applicants submit that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 C.F.R. § 1.137(b) was unintentional, and that any time Applicants spent discerning options to petition for the withdrawal of the holding of abandonment was incidental to the unintentional loss or mutilation of the papers Applicants deposited with the U.S. Postal Service on June 11, 2001.

Nonetheless, Applicants hereby petition to revive the above-mentioned Application, and note that a separate communication is being filed herewith responsive to the February 13, 2001, Office Action, including: 1) a Request (and \$460.00 check) for a three month extension in which to respond to the outstanding Office Action; 2) a new Appointment of Associate Attorneys; and 3) an appropriate Amendment Transmittal.

Thus, enclosed please find:

1. a check in the amount of \$640.00 to cover the petition fee by a small entity to revive an unintentionally abandoned Application as set forth in 37 C.F.R. § 1.17(m);
2. an Amendment And Response to the February 13, 2001, Office Action;
3. a Request For a Three Month Extension of Time;
4. a check for \$460.00 to cover the extension of time as set forth in 37 C.F.R. § 1.17(a)(3);
5. an Appointment of Associate Attorney; and

6. an Amendment Transmittal.

A small entity statement has been previously filed with the Office in a communication dated October 27, 1999.

The Commissioner is hereby authorized to charge any additional fees or credit overpayments to our Deposit Account No. 08-1290. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: December 13, 2001



Thomas J. Bordner  
Registration No. 47, 436

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
608/218-6900



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Serial No.:  
Filed:  
Entitled:

Michael Karin *et al.*  
09/377,795  
08/20/99  
Gamma Subunit of Cytokine Responsive IKB-Alpha Kinase Complex  
and Methods of Using Same

Group No. 1635  
Examiner: Schmidt, M.

AMENDMENT TRANSMITTAL

Assistant Commissioner for Patents  
Washington, D.C. 20231

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I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
Dated: December 13, 2001	By: <u>Mary Ellen Waite</u> Mary Ellen Waite

Sir or Madam:

Transmitted herewith is an amendment for this application. The fee has been calculated as shown below.

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE	ADDITIONAL FEE
Total Claims	5	—	29	0	×	18.00	\$0.00
Independent Claims	2	—	8	0	×	84.00	\$0.00

Three Month Extension of Time \$920.00

**TOTAL DUE \$460.00**

1. A check in the amount of \$460.00 is attached.
2. Petition to Revive Unintentionally Abandoned Application under 37 C.F.R. § 1.137(b) and a check in the amount of \$640.00 is attached to cover said fee.
3. Please charge any additional fees, including any fees necessary for extensions of time, or credit overpayment to Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.
4. Petition for extension of time. The undersigned attorney of record hereby petitions for an extension of time pursuant to 37 C.F.R. § 1.136, as may be required, to file this response.

Dated: December 13, 2001

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By: Thomas J. Bordier  
Thomas J. Bordier  
Registration No. 47,436

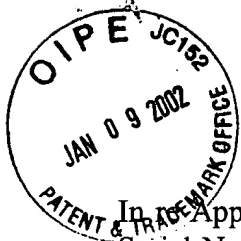
MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
415/904-6500

**UNITED STATES PATENT & TRADEMARK OFFICE**  
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REQUEST FOR PATENT FEE REFUND											
1 Date of Request: <u>2/11/02</u>		2 Serial/Patent # <u>09/377,795</u>									
3 Please refund the following fee(s):		4 PAPER NUMBER	5 DATE FILED	6 AMOUNT							
	Filing			\$							
	Amendment			\$							
<input checked="" type="checkbox"/>	Extension of Time	12	1/9/02	\$ 460							
	Notice of Appeal/Appeal			\$							
	Petition			\$							
	Issue			\$							
	Cert of Correction/Terminal Disc.			\$							
	Maintenance			\$							
	Assignment			\$							
	Other			\$							
		7 TOTAL AMOUNT OF REFUND		\$ 460							
10 REASON:		8 TO BE REFUNDED BY:									
	Overpayment	<input type="checkbox"/> Treasury Check									
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No EOT after <del>pat</del> off abandoned.											
11 REFUND REQUESTED BY:											
TYPED/PRINTED NAME: <u>RC TANG</u>		TITLE: <u>Petitioner</u>									
SIGNATURE: <u>[Signature]</u>		PHONE: <u>703 308-0763</u>									
OFFICE: <u>Petitioner</u>											
***** THIS SPACE RESERVED FOR FINANCE USE ONLY: *****											
APPROVED: <u>Alicia Kelly</u>		DATE: <u>3-4-02</u>									

Instructions for completion of this form appear on the back. After completion, attach white and yellow copies to the official file and mail or hand-carry to:

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Refund Branch  
Crystal Park One, Room 802B



**PATENT**  
U.S. Pat. Appl. Ser. No.: 09/377,795  
Attorney Docket No.: UCSD-04523

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Application of: Karin *et al.*

Serial No.: 09/377,795

Filed: 08/20/99

Entitled: **Gamma Subunit of Cytokine Responsive IKB-Alpha Kinase  
Complex and Methods of Using Same**

Group No.: 1635

Examiner: Mary Schmidt

**AMENDMENT AND RESPONSE TO OFFICE ACTION  
MAILED FEBRUARY 13, 2001**

Assistant Commissioner for Patents  
Washington, D.C. 20231

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)**

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Dated: December 13, 2001

By: 

Mary Ellen Waite

Dear Examiner:

This communication is responsive to the Office Action mailed February 13, 2001. A petition for a one month extension of time to respond to the Office Action accompanies this communication. Applicants respectfully request reconsideration of the application in view of the following amendments and remarks. Please amend the application as follows:

Adjustment date: 03/04/2002 AKELLEY  
01/10/2002 STEFFERA 00000111 09377795  
02 FC:217 -460.00 OP

**In The Claims:**

Please cancel Claims 12, 16, and 17.

Repl. Ref: 03/04/2002 AKELLEY 0011205100  
DAW:001290 Name/Number:09377795  
FC: 704 \$460.00 CR

Please rewrite Claims 11 and 13-15 to read as follows:

11. An isolated human IKK- $\gamma$  nucleic acid molecule, encoding a polypeptide having at least 87% amino acid identity with SEQ ID NO:2.

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01/10/2002 STEFFERA 00000111 09377795

02 FC:217

460.00 OP

13. The isolated human IKK- $\gamma$  nucleic acid molecule of Claim 11, comprising a nucleotide sequence encoding amino sequence SEQ ID NO:2.

14. The isolated human IKK- $\gamma$  nucleic acid molecule of Claim 13, comprising nucleotides 149 to 1408 of SEQ ID NO:1.

15. The isolated human IKK- $\gamma$  nucleic acid molecule of Claim 13, comprising SEQ ID NO:1.

Please add Claim 30.

30. A human origin antisense polynucleotide, comprising a nucleotide sequence complementary to SEQ ID NO:1.

**R E M A R K S**

The Examiner requested that the Applicants supply a duplicate 1449 form and legible copies of the references cited therein. Applicants have complied with the Examiner's request. Accompanying this communication is a duplicate 1449 form and legible copies of the references cited therein. Applicants respectfully request the Examiner consider these references and make them of record in the present application.

Claims 11-17 were pending in the present application. In the Office Action mailed February 13, 2001, all of the pending claims were rejected. For clarity, the rejections at issue are set forth below in the order in which they were presented and are herein addressed:

- I. Claims 11-15 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite;
- II. Claims 11-17 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not conforming to the written description requirement;
- III. Claims 11-17 stand rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Yamaoka *et al.* (Cell, 93:1231-124 [1998]), GenBank Accession Number AF069542, and Medline Accession Number 98319237; and
- IV. Claims 16 and 17 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Hillier *et al.* (GenBank Accession Number AA402683); and
- V. Claims 16 and 17 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Marra *et al.* (GenBank Accession Number AA387553).

Applicants believe that the amendments and remarks presented herein overcome these rejections and place the application in condition for allowance.

In this communication, Claims 11 and 13-15 have been amended. The amendments to these claims were made in order to further business interests and the prosecution of the present application, and not in acquiescence to the Examiner's arguments, and while reserving the right to prosecute the original (or broader) claims in the future. Also in this communication, Applicants have cancelled Claims 12, 16, and 17 without prejudice to future prosecution of these (or broader) claims in subsequent applications.

In conformity with current U.S. Patent and Trademark Office rules set forth in 37 C.F.R. §1.121 (c)(1)(i-ii)) Applicants have attached hereto at Appendix 1 a sperate sheet



entitled "Version With Markings To Show Changes Made" to present the various changes made to the pending Claims. Applicants have also attached hereto at Appendix 2 a clean version of the entire set of pending Claims, as amended by this communication, for the Examiner's convenience.

**I. The Pending Claims Are Definite**

Claims 11-15 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention. In particular, the Examiner argues that "[c]laims 11-15 are indefinite for [reciting] the language 'substantially the same amino acid sequence'" because the specification allegedly fails to define the meets and bounds of this term. (*See*, Office Action, page 3). Applicants must respectfully disagree.

Nonetheless, in order to further business interests and the prosecution of the present application, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original (or broader) claims in the future, Applicants have amended Claim 11 to remove the language the Examiner finds objectionable. Applicants believe that the amended claims are definite and respectfully request that the rejection be withdrawn.

**II. The Pending Claims Satisfy The Written Description Requirement**

Claims 11-17 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to satisfy the written description requirement. Applicants note that the Examiner admits the Specification teaches isolated human IKK- $\gamma$  nucleic acid and methods of its administration. (Office Action, page 3). The Examiner argues that Claims 11-17 are indefinite for reciting the term "substantially the same as." The Examiner also argues that while the Specification teaches human IKK-gamma, the pending claims encompass IKK-gamma from other species. (*See*, Office Action, page 4). Applicants must respectfully disagree with both of the Examiner's arguments. In addition, the term "substantially the same as" no longer appears in Claim 11. Thus, this part of the Examiner's rejection is moot.

Applicants have amended the pending claims to recite, in pertinent part, that the nucleic acids, polynucleotides, and antisense polynucleotides, respectively, are of human

origin. Applicants made these amendments in order to further business interests and the prosecution of the present application, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original (or broader) claims in the future.

However, Applicants note that the present claims encompass some modifications to the disclosed IKK- $\gamma$  subunit. (See, Specification pages 19-20, among other places). Thus, the modifications (e.g., substitutions, additions, deletions, etc.) to the IKK- $\gamma$  subunits that are disclosed in the present application remain within the scope of the presently claimed invention and should not be considered as rendering the claimed subject matter of non-human origin.

For the reasons stated above, Applicants submit that the present claims satisfy the written description requirements of 35 U.S.C. §112. Applicants respectfully request that the present rejection be withdrawn.

### **III-V. The Claims are Novel**

The Examiner rejected Claims 11-17 under 35 U.S.C. §102(a) as allegedly being anticipated by Yamaoka *et al.* The Examiner also rejected Claims 16 and 17 under 35 U.S.C. §102(b) as allegedly being anticipated by references to Hillier *et al.* and Marra *et al.*

Applicants submit that the cited references fail to teach every element of the present claims. The Federal Circuit has held that "[i]nvalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference . . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." (*Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 [Fed. Cir. 1991]); See also, MPEP §2131.

The present Claims recite, in pertinent part, nucleic acids, polynucleotides, and antisense polynucleotides, respectively, not taught by Yamaoka *et al.* An analysis of the gene and gene product reported in Yamaoka *et al.* (GenBank Accession number AF069542, and Medline Accession No. 983119237, respectively) with SEQ ID NO:1 and SEQ ID NO:2 as described and claimed in the present invention reveals that the gene and gene product described by Yamaoka differ by about 15% and 14%, respectively, from SEQ ID NOs:1 and 2. (See, Appendices 3 and 4). Thus, the work described in Yamaoka *et al.* is directed to a different gene and corresponding gene product than taught and presently claimed.


As stated above, anticipation requires that a single reference either expressly or inherently teaches every element of the claimed invention. Since the Yamaoka *et al.* reference fails to teach every element of the present claims, it does not anticipate the presently claimed invention (including new Claim 30).

The Examiner argues that Hillier *et al.* and Marra *et al.* each anticipate Claims 16 and 17. This rejection is moot in light of Applicants cancellation, without prejudice, of Claims 16 and 17 in this communication. Applicants reserve the right to pursue these claims in a subsequent application. Should the Examiner apply Hillier *et al.* and Marra *et al.* to new Claim 30, Applicants submit that neither of these references anticipate SEQ ID NO:1 as it is recited in new Claim 30.

### CONCLUSION

For the reasons set forth above, it is respectfully submitted that Applicants' claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: December 13, 2001

  
Thomas J. Bordner  
Registration No. 47,436

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 305  
San Francisco, California 94105

## **Appendix 1**

### **Version With Markings To Show Changes Made**

#### **In the Claims**

Please cancel Claims 12, 16, and 17.

Please amend Claims 11 and 13-15 as follows:

11. (Amended) An isolated human IKK- $\gamma$  nucleic acid molecule, [comprising a nucleotide sequence] encoding a polypeptide having at least 87% amino acid identity with [encoding substantially the same amino acid sequence as] SEQ ID NO:2.

13. (Amended) The isolated human IKK- $\gamma$  nucleic acid molecule of [claim] Claim 11, comprising a nucleotide sequence encoding amino sequence SEQ ID NO:2.

14. (Amended) The isolated human IKK- $\gamma$  nucleic acid molecule of [claim] Claim 13, comprising nucleotides 149 to 1408 of SEQ ID NC:1.

15. (Amended) The isolated human IKK- $\gamma$  nucleic acid molecule of [claim] Claim 13, comprising SEQ ID NO:1.

Please add Claim 30.

30. A human origin antisense polynucleotide, comprising a nucleotide sequence complementary to SEQ ID NO:1.

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**Appendix 2**

11. (Amended) An isolated human IKK- $\gamma$  nucleic acid molecule, comprising a nucleotide sequence having at least 87% amino acid identity with SEQ ID NO:2.

13. The isolated human IKK- $\gamma$  nucleic acid molecule of Claim 11, comprising a nucleotide sequence encoding amino sequence SEQ ID NO:2.

14. The isolated human IKK- $\gamma$  nucleic acid molecule of Claim 13, comprising nucleotides 149 to 1408 of SEQ ID NO:1.

15. The isolated human IKK- $\gamma$  nucleic acid molecule of Claim 13, comprising SEQ ID NO:1.

30. A human origin antisense polynucleotide, comprising a nucleotide sequence complementary to SEQ ID NO:1.

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In re Application of: Michael Karin *et al.*

Serial No.: 09/377,795

Group No.: 1635

Filed: 08/20/99

Examiner: Mary Schmidt

Entitled: **Gamma Subunit of Cytokine Responsive IKB-Alpha Kinase Complex  
and Methods of Using Same**

REQUEST FOR EXTENSION OF TIME

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I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
Dated: <u>December 13, 2001</u>	By: <u>Mary Ellen Waite</u> Mary Ellen Waite

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir or Madam:

Applicants hereby petition for a three month extension of time to answer the outstanding Office Action mailed 02/13/01 regarding the above-identified patent application. Please find a check enclosed in the amount of **\$445.00** to cover the extension fee for filing a Response within the third month.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. **08-1290**. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: December 13, 2001

By: Thomas J. Bordner  
Thomas J. Bordner  
Registration No. 47,436

MEDLEN & CARROLL, LLP  
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In re Application of: Michael Karin *et al.*      Group No.: 1635  
Serial No.: 09/377,795      Examiner: Mary Schmidt  
Filed: 08/20/99  
Entitled: **Gamma Subunit of Cytokine Responsive IKB-  
Alpha Kinase Complex and Methods of Using  
Same**

**APPOINTMENT OF ASSOCIATE ATTORNEYS**

Assistant Commissioner for Patents  
Washington, D.C. 20231

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Dated: <u>December 13, 2001</u>	By:  Mary Ellen Waite

Sir or Madam:

Pursuant to 37 C.F.R. § 1.34(b), as Principal Attorney, I appoint as Associate Attorney, the members of the firm of MEDLEN & CARROLL, LLP, a firm composed of:

Jaen Andrews	(Reg. No. 35,051)
Tanya Arenson	(Reg. No. 47,391)
Thomas J. Bordner	(Reg. No. 47,436)
Mary Ann Brow	(Reg. No. 42,363)
Thomas C. Howerton	(Reg. No. P-48,650)
Thomas W. Brown	(Reg. No. P-50,002)

Please address all communications to:

Thomas J. Bordner  
MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
Telephone: 608/218-6900  
Facsimile: 608/218-6910

The Assistant Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: 12/13/01

By: 

David A. Casimir  
Registration No. 42,395  
Attorneys for Applicant

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